K013462

JAN 11 2002

510(k) SUMMARY

A. Device Proprietary Name: Device Common Name:	Hydrofera Bacteriostatic Wound Dressing Wound dressing external use
Description:	Hydrofera Bacteriostatic Wound Dressings are blue in color and manufactured from a pure white synthetic material with absorbent sponge-like characteristics. The two pigments have been added to render the material bacteriostatic. Please see Instructions for Use
B. Establishment Registration Number:	1225532
Establishment Name & Address:	Hydrofera LLC 322 Main Street Willimantic CT 06226
C. Device Classification of Category:	Unclassified
D. Performance standards:	None
E. Proposed Labeling:	Draft Labeling is attached
F. Substantial Equivalence:	The subject wound dressing have the same intended use as the predicate device: Ultrafera wound dressing(K964614) and Hydrofera Bacteriostatic Nasal Dressing (K983276)
G. Materials:	Hydrofera Bacteriostatic Wound Dressings are comprised of absorbent polyvinyl alcohol PVA, free formaldehyde <5 ppm)Methylene Blue(less than or equal to 0.00025 gr/gr) and Crystal Violet (less than or equal to 0.00025gr/gr)
H. Sterility:	Hydrofera Bacteriostatic Wound Dressings will be sterilized by either gamma or electron beam radiation to an SAL 10-6. The process will be followed in accordance with Method I Bioburden and validated with subsequent quarterly dose audits.
I. Packaging:	Each Hydrofera Bacteriostatic Wound Dressing will be individually packaged in a Mylar to Poly Tyvek (chevron) pouch.
J. S & E Summary:	Hydrofera LLC certifies that safety and effectiveness information will be provided for this marketed device upon request by interested persons.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2002

Heather H. Bond
Director Polymer Technology
Hydrofera, LLC.
322 Main Street
Willimantic, Connecticut 06226

Re: K013462
Trade Name: Hydrofera Bacteriostatic Wound Dressing
Regulation Name: Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 15, 2001
Received: October 18, 2001

Dear Ms. Bond:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Neil R.P. Ogden for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K013462

DEVICE NAME: HYDROFERA BACTERIOSTATIC WOUND DRESSING

INDICATIONS FOR USE:

Hydrofera Bacteriostatic Wound Dressings are intended as external dressings for use in local management of wounds such as pressure ulcers, donor sites, venous stasis ulcers, arterial ulcers, diabetic ulcers, abrasions, lacerations, and superficial b post-surgical incisions, and other external wounds inflicted by trauma.

NRO for CMW

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013462

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use + OR Over-The-Counter-Use ___
(Per 21 CFR 801.109) (Optional Format 1-2-96)